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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,355	11/03/2003	Jackson Streeter	ACULSR.028A	5229
20995	7590	07/25/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			KIM, TAEYOON	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/700,355	Applicant(s) STREETER, JACKSON	
	Examiner Taeyoon Kim	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/03/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-19 are pending.

Election/Restrictions

1. Applicant's election without traverse of Group III (claims 11-19) in the reply filed on Jun. 26, 2006 is acknowledged.

Claims 1-10 are withdrawn from consideration, as being drawn to non-elected subject matter. Claims 11-19 have been considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 11-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the first line of Claim 11, the terms "accelerating the production of a vaccine" are not clearly pointing out in the application. The terms "accelerating the production of a vaccine" do not particularly point out and distinctly claim the subject matter. These terms can be interpreted as either a shortening the time for the vaccine production or increase the amount of vaccine produced after vaccination of irradiated cells into the host.

In the 6th-7th lines of Claim 11, it is not clear what the terms "useful in a vaccine" point out. The term "useful" does not distinctly claim the subject matter. This can be

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interpreted that the resulting cells in the claims are useful as a vaccine itself or useful for vaccination into a host animal.

Claims 18 and 19 recites the limitation "the treatment" in the first line of each claim. There is insufficient antecedent basis for this limitation in the claim.

Since how the treatment with electromagnetic energy to the cells accelerates the production of a vaccine, and how cells in culture after electromagnetic energy treatment are useful in a vaccine are not clearly pointed out in the application, the Examiner interprets claim 11 and its dependents as "a method for accelerating the production of a vaccine comprising delivering an effective amount of electromagnetic energy having a wavelength in the visible to near-infrared wavelength range and a power density of at least about 0.01 mW/cm² to cells in a culture" for the search purpose.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 11-15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Salansky et al. (U.S. Patent 6,063,108).

Claim 11 is drawn to a method for accelerating the production of vaccine comprising delivering an effective amount of electromagnetic energy having a

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wavelength in the visible to near-infrared wavelength range and a power density of at least about 0.01 mW/cm² to cells in culture.

Claims 12-19 are drawn to a limitation of the power density in claim 11 being about 0.01 mW/cm² to about 100 mW/cm² (claim 12), about 0.01 mW/cm² to about 15 mW/cm² (claim 13), the wavelength of light energy being about 630 nm to about 904 nm (claim 14) or about 780 nm to about 840 nm (claim 15), pulsed delivery of light energy (claim 17), and light energy treatment being two or more periods (claim 18) with a duration of treatment being about 30 seconds to about 2 hours (claim 19).

Salansky et al. teach a method delivering an effective amount of electromagnetic energy with a wavelength of 630 nm to 700 nm (column 3, line 48: claim 14) or 800 nm (column 3, line 48: claim 15) to cell culture (see column 8, lines 22-25), wherein light energy having a power density at the range of 0.2-10 mW/cm² (see table 2: claims 12 and 13), resulting in activation of cell metabolism, respiration and secretory activity and also protein synthesis (column 26, line 61 through column 27, line 40). Salansky et al. also teach the treatment with a light energy can be multiple treatment periods (see Table 9: claim 18) and the duration of pulse (exposure time) is disclosed as 300-400 seconds (see Table 8: claim 19).

Although Salansky et al. do not specifically teach the method wherein the cells are used for a vaccine, the reference does teach that the method may activate production of immunoglobulins in the immune system (see column 27, lines 19-26). Thus, the cells treated by the method of Salansky et al. are considered to be "useful in a vaccine" as claimed by applicant. Furthermore, while Salansky et al. do not identify a

method to accelerate production of a vaccine, it is noted that the claims do not require production of a vaccine, but merely state that the cells treated by the method are useful as such. Moreover, by practicing the methods of Salansky et al., one in the art would inherently be practicing the claimed method, as the steps are the same.

Therefore, the reference anticipates the claimed subject matter.

4. Claims 11, 12, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by van Breugel et al. (Lasers in Surgery and Medicine, 1992, 12:528-537).

Claim 11 is directed to a method for accelerating the production of vaccine comprising delivering an effective amount of electromagnetic energy having a wavelength in the visible to near-infrared wavelength range and a power density of at least about 0.01 mW/cm^2 to cells in culture.

Claims 12, 14 and 16 are directed to a limitation of the power density in claim 11 being about 0.01 mW/cm^2 to about 100 mW/cm^2 (claim 12), the wavelength of light energy being about 630 nm to about 904 nm (claim 14) and a light source being placed on top of a culture incubator (claim 16).

Van Breugel et al. teach a laser irradiation to fibroblasts in culture with a wavelength of 630 nm (see abstract: claims 11 and 12) and a power density in a range of 0.55 to 5.98 mW (see abstract: claims 11 and 14), and the light source was at the top surface of a cell culture incubator (see Fig. 1: claim 16).

Although van Breugel et al. do not identify a method to accelerate production of a vaccine, it is noted that the claims do not require production of a vaccine, but merely

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state that the cells treated by the method are useful as such. Moreover, by practicing the methods of van Breugel et al., one in the art would inherently be practicing the claimed method, as the steps are the same. Furthermore, while van Breugel et al. do not particularly teach the method wherein the cells are used for a vaccine, this limitation has been interpreted as an intended use. The intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the composition of the prior art. In the instant case, the intended use fails to create a structural difference, thus, the intended use is not limiting (see M.P.E.P. §2111.02). Please also note that when applicant claims a composition in terms of function, and the composition of the prior art appears to be the same, the Examiner may make rejections under both 35 U.S.C. 102 and 103 (see M.P.E.P. §2112).

Therefore, the reference anticipates the claimed subject matter.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taeyoon Kim
Patent Examiner
Art Unit 1651



RUTH DAVIS
PRIMARY EXAMINER